

## REMARKS

Claims 24-32 and 37 are pending in this application. Claims 1-23 and 33-35 have previously been cancelled without prejudice. Claim 36 has been cancelled without prejudice with this amendment. Claims 24, 26 and 30 have been amended herein. Claim 24 has been amended to clarify that the second wire guide and second introducer are advanceable independent of the first introducer. Claim 24 also has been amended to recite that the first introducer and the second introducer are placed in a staggered, adjacent configuration in a working channel of an endoscope. A typographical error has also been corrected in claim 24. Claim 26 has been amended to clarify that the first and second introducers are disposed in a staggered, adjacent configuration in a working channel of an endoscope. Claim 26 also recites that the second wire guide is advanceable external to and independent of the first stent. Claim 30 has been amended to clarify that the first stent and the second stent are provided in a staggered, adjacent and independently advanceable configuration in a working channel of an endoscope. No new matter has been added with these amendments. Support for these amendments may be found throughout the specification and in the FIGS., for example, paragraph 0050 and FIG. 13. Favorable consideration and allowance are respectfully requested.

### **I. Claim Rejections Under 35 U.S.C. §102**

Claims 24-27, 29 and 37 have been rejected under 35 U.S.C. §102 (e) as being anticipated by Hilaire et al. (U.S. (2005/0085845)). Applicants have provided a discussion of the relevance of the Hilaire et al. reference. However, Applicants do not want the discussion of the Hilaire et al. reference to be construed as an admission that the reference is prior art. Applicants reserve the right to later provide arguments as to whether the Hilaire et al. reference is prior art.

Applicants respectfully traverse the rejection based on Hilaire et al. Applicants respectfully request reconsideration of the rejected claims in light of the traversals and the claim amendments discussed below.

Applicants' claim 24 requires that the second wire guide and second introducer are advanceable independent of the first introducer. Applicants' claim 26 requires that the

second wire guide is advanceable external to and independent of the first stent. Claims 24 and 26 also require that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope. Hilaire et al. fails to teach or suggest these elements.

Hilaire et al. is directed to a catheter system including a releasable linking device for holding the first and second balloon catheter in a side-by-side configuration and aligned with one another along a longitudinal axis. "The linking device allows the catheters to be moved as a unit." (Abstract.) In addition, as shown in FIG. 2, the flexible tubular extension 134 of the second balloon catheter 104 is inserted into the main stent 170 of the first balloon catheter 102. Similarly, as shown in FIG. 5, the second steerable guidewire 142 is inserted into the main stent 170 of the first balloon catheter 102. (Paragraphs 0080 and 0081.) In other words, the device of Hilaire et al. includes catheters 102 and 104 that are connected by both a releasable linking device and by insertion of the guidewire of the second catheter through the stent of the first catheter so that the first and second catheters must advance together.

Clearly, Hilaire et al. teaches away from advancing the second wire guide and second introducer independent of the first introducer as claimed in claim 24. Hilaire et al. also fails to teach or suggest that the second wire guide is advanced external to and independent of the first stent as claimed in claim 26. In fact, even if the releasable linking device is released, the second guidewire of Hilaire et al. is still connected through the first stent and is advanced together with the first stent. Hilaire et al. clearly fails to teach or suggest a second wire guide and catheter independently advanceable from the first introducer and a second wire guide advanceable external to and independent of a first stent. In addition, Hilaire et al. fails to teach or suggest that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope.

Thus, Applicants respectfully assert that claims 24-27, 29 and 37 are not anticipated by Hilaire et al. Applicants respectfully request the rejection of claims 24-27, 29 and 37 under 35 U.S.C. §102(e) be withdrawn.

## **II. Claim Rejections Under 35 U.S.C. §103**

### **A. Claim 28**

Claim 28 has been rejected as being unpatentable over Hilaire et al. under 35 U.S.C. §103 (a).

Applicants respectfully traverse the rejection of claim 28. Claim 28 depends from claim 26. Hilaire et al. has been discussed above and fails to teach or suggest that the second wire guide is advanced external to and independent of the first stent.

Thus, for the same reasons, Applicants respectfully request that the rejection of claim 28 under 35 U.S.C. §103(a) be withdrawn.

### **B. Claim 36**

Claim 36 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Hilaire et al. in view of Colgan et al. (U.S. 2003/0040789).

Claim 36 has been cancelled rendering the rejection of claim 36 moot.

However, Applicants have provided a discussion of Colgan et al. since claims 24, 26 and 30 require that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope.

Colgan et al. has been cited for providing an endoscope having a working channel. Colgan et al. is directed to a system for delivering a medical prosthesis including a single catheter having a stent mounted at the distal end that is released into the body lumen by movement of an outer sheath covering the stent in the proximal direction. Colgan et al. does not teach or suggest a first AND a second introducer. Colgan et al. further fails to teach or suggest that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope.

Applicants respectfully assert that Colgan et al. alone or in combination with the references of record fails to teach or suggest all of the recited elements in Applicants' claims 24-32 and 37.

### **C. Claims 24-32 and 37**

Claims 24-32 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shakhovich (U.S. 5,669,924).

Applicants respectfully traverse the rejection based on Shaknovich. Applicants respectfully request reconsideration of the rejected claims in light of the traversals and the claim amendments discussed above.

Applicants' claim 24 requires that the first and second introducers are disposed in a staggered, adjacent configuration in a working channel of an endoscope wherein the first proximal portion is disposed distal to the second proximal portion, the staggered, adjacent configuration having an overall diameter that is less than the sum of a first distal portion diameter and a second distal portion diameter. Applicants' claim 26 requires that the first and second introducers be disposed in a staggered, adjacent configuration in a working channel of an endoscope wherein the first stent is disposed distal to the second stent, the staggered, adjacent configuration having an overall diameter that is less than the sum of a first distal portion diameter and a second distal portion diameter. Claim 30 requires that a first stent and a second stent are provided in a staggered, adjacent, independently advanceable configuration in a working channel of an endoscope wherein the first stent is distal to the second stent; the staggered, adjacent configuration having an overall diameter that is less than the sum of adjacent first stent portion and second stent portion diameters.

The advantages of the staggered configuration are clearly discussed in Applicants' specification at paragraph 0044, reproduced in part below.

The introducers 10, 20 are adapted so that the overall diameter of the pair of introducers is minimized. The overall diameter of the pair of introducers 10, 20 is minimized by juxtaposing the stent retaining area of a first introducer 10 with the portion proximal to the stent retaining area of a second introducer 20. As can be seen in FIG. 12, the sum of the first proximal outer diameter and the second distal outer diameter is less than the inner diameter of the working channel 8a of the endoscope 8." (Paragraph 0044.)

The reduced overall diameter of the pair of introducers is smaller than the individual diameters and allows for a smaller working channel diameter that can accommodate the pair of introducers. The smaller working channel diameter also allows for a smaller diameter endoscope overall.

As acknowledged by the Examiner, Shaknovich fails to disclose the step of placing the first and second introducers in a staggered, adjacent configuration. Shaknovich discloses stent delivery systems sharing the common feature of a Y-shuttle having a Y-

shaped stent deployment segment. (Col. 8, lines 61-63.) Shaknovich discloses the advantages of the Y-shuttle over the previous delivery systems using only introducers. For delivery, the trunk of the Y-shaped deployment segment, and both arms of the Y-shaped deployment segment are folded upward and together to fit inside the guiding catheter to be used during the procedure. In fact, Shaknovich teaches away from simultaneous overlapping stent placement without the use of the Y-shuttle in the discussion of the prior art where Shaknovich suggests that simultaneous overlapping stent placement may risk disruption of the main trunk vessel proximal to the origin of the side branch. Concerns and undesirable consequences of trapping of one of the delivery stems by the other stent with any attempted simultaneous non-overlapping deployment are illustrated in FIGS. 10 and 11. (Col. 6, lines 16-18 and 24-26, see also Col. 8, lines 23-37.) Shaknovich clearly fails to teach or suggest adjacent, staggered and independently advanceable first and second introducers or stents. Shaknovich also fails to teach or suggest that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope.

Applicants respectfully request the rejection of claims 24-32 and 37 under 35 U.S.C. §103(a) be withdrawn.

**D. Claim 36**

Claim 36 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Shaknovich in view of Colgan et al.

Claim 36 has been cancelled rendering the rejection of claim 36 moot. A discussion of the Colgan et al. reference has been provided above.

Applicants respectfully request the rejection of claim 36 under 35 U.S.C. §103(a) be withdrawn.

**E. Claims 30-32**

Claims 30-32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hilaire et al. in view of Shaknovich.

Applicants respectfully traverse the rejection based on Hilaire et al. in view of Shaknovich. Applicants respectfully request reconsideration of the rejected claims in light of the traversals and the claim amendments discussed below.

Applicants' claim 30 requires that a first stent and a second stent be provided in a staggered, adjacent, independently advanceable configuration in a working channel of an endoscope wherein the first stent is distal to the second stent; the staggered, adjacent configuration having an overall diameter that is less than the sum of adjacent first stent portion and second stent portion diameters. Hilaire et al. and Shaknovich, individually or together, fail to teach or suggest these elements.

Hilaire et al. and Shaknovich have both been discussed in detail above. Hilaire et al. discloses a releasable linking device for advancing the first and second introducers together and that the second guidewire of Hilaire et al. is still connected through the first stent and is advanced together with the first stent. Shaknovich discloses a Y-shaped deployment segment, and both arms of the Y-shaped deployment segment are folded upward and together to fit inside the guiding catheter to be used during the procedure. Hilaire et al. and Shaknovich, individually or together, fail to teach or suggest an adjacent, staggered independently advanceable configuration in a working channel of an endoscope for the first and second stents.

Thus, Applicants respectfully assert that the claimed invention in claims 30-32 is not obvious over Hilaire et al. in view of Shaknovich. Applicants respectfully request the rejection of claims 30-32 under 35 U.S.C. §103(a) be withdrawn.

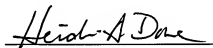
## SUMMARY

Having carefully addressed the Examiner's rejections, Applicants respectfully assert that the application is in condition for allowance. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

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